In the United States Court of Federal Claims office of special masters No. 19-0890V

UNPUBLISHED

L.M.,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: May 12, 2022

Special Processing Unit (SPU); Findings of Fact; Ruling on Entitlement; Influenza (Flu); Shoulder Injury Related to Vaccine Administration (SIRVA).

Danielle Anne Strait, Maglio Christopher & Toale, PA, Seattle, WA, for Petitioner.

Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On June 18, 2019, L.M. filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act") alleging that she suffered a left shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered to her on December 9, 2016. Petition, ECF No. 1 at 1, 4. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished opinion contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the opinion will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that a preponderance of evidence supports the conclusion that Petitioner's pain and reduced range of motion were limited to her left shoulder, and that Petitioner is otherwise entitled to compensation for a left SIRVA.

I. Relevant Procedural History

After initiating her claim, Petitioner filed additional records and an amended statement of completion in June 2019. ECF Nos. 6-7. During the winter and spring of 2020, Respondent filed status reports stating that additional time was needed to conduct a medical review of this case and expressing his inability to articulate his position on the merits. ECF Nos. 15, 19. On May 12, 2020, Respondent formally requested an additional 90 days to indicate how he intended to proceed in this case. ECF No 21. In addition to noting her objection, Petitioner filed a motion for a ruling on the record regarding entitlement ("Motion") on May 13, 2020. ECF Nos. 22, 23.

Respondent's request for additional time was denied, and a ruling on Petitioner's Motion was deferred. ECF No. 24; Non-PDF order, dated May 15, 2020. On May 27, 2020, Respondent filed a status report indicating that no "factual or legal issues that require additional support or further factual development" had been identified by his counsel. ECF No. 25. Finally, on July 29, 2020, Respondent completed his formal review of the claim and invited settlement discussions. ECF No. 26. The parties spent the next several months attempting to settle this case, but Petitioner later filed a status report informing me that their efforts proved unsuccessful. ECF No. 35. After a status conference on February 18, 2021, Petitioner was ordered to file her renewed motion for a ruling on the record regarding entitlement ("Amended Motion"). ECF No. 36.

On February 22, 2021, Petitioner filed her Amended Motion contending that she met her burden of proof for both a Table SIRVA and off-Table claim based on the medical records. ECF No. 37. Respondent filed his response ("Response") on April 7, 2021. ECF No. 39. In it, he argues that Petitioner is not entitled to compensation for SIRVA because her pain was not limited to her vaccinated shoulder. *Id.* Petitioner filed her reply on April 21, 2021. ECF No. 40.

II. Relevant Factual Evidence

I have fully reviewed the evidence, including all medical records, medical literature, and the parties' briefing. I find most relevant the following:

• Petitioner received a flu shot in her left deltoid on December 9, 2016. Ex. 1; Ex. 4 at 20; Ex. 8.

- On December 19, 2016 (10 days post-vaccination), Petitioner telephoned her primary care provider. Ex. 4 at 71-72. She reported that she experienced soreness and numbness in her left hand shortly after receiving the flu shot on December 9, 2016. *Id.* Petitioner further reported that although these symptoms subsided after three days, there was bruising at the injection site and her left shoulder was sore. *Id.* at 72.
- Petitioner presented to her primary care provider on December 22, 2016, with complaints of left shoulder pain following receipt of a flu shot. Ex. 4 at 86-87. The medical notes from this visit indicate that although Petitioner reported shoulder pain as well as numbness and tingling down her arm after the vaccination, "the numbness and tingling has since resolved[,] but the left shoulder is still stiff and when adducted across her body[,] she feels pain 'deep' in her left shoulder." Id. at 87. It was further indicated that "[d]uring the injection[,] the MA noticed the plunger on the syringe injected rather quickly and alerted the MD at the time." Id.
- A January 9, 2017 telephone contact summary, drafted by Nurse Practitioner ("NP") Terece Hahn, documents Petitioner's report of continued left arm pain. Ex. 4 at 119. NP Hahn's progress note reflects that "[Petitioner's December 9, 2016] injection event will be documented . . . due to the iatrogenic cause of the pain." *Id.* at 120. She further noted that "[i]njury mechanism and history is presumed to be inflammatory in nature but due to the longevity and severity of the presentation of injury, further work up is indicated." *Id.*
- Petitioner presented to Dr. Heather Readhead for continued left shoulder pain on January 19, 2017. Ex. 4 at 148-176. During this visit, Petitioner described the pain as sharp and noted that her injury inhibited full active range of motion. *Id.* at 149. Petitioner was assessed with "vaccine related shoulder dysfunction likely secondary to injection of fluid into subdeltoid bursa causing periarticular inflammatory responses, subacromial bursitis and start of adhesive capsulitis." *Id.* at 155, 162.
- On February 3, 2017, Petitioner presented to Jason A. Romriell, PA-C at Northwest Orthopaedic Specialists. Ex. 6 at 10. PA Romriell documented Petitioner's report of "pain that went all the way down her arm" immediately following her December 2016 flu shot. *Id.* He further noted that "ever since then, she has had pain in her shoulder as well as pain radiating down into her hand. She does not describe this as a numbness tingling pain." *Id.* PA Romriell's impression was "left shoulder pain

after a vaccine" and his treatment plan included obtaining an MRI to evaluate Petitioner's rotator cuff. *Id.*

- Petitioner presented for a follow-up appointment with PA Romriell on February 16, 2017. Ex. 6 at 11. The notes documenting this appointment indicate that Petitioner's February 13, 2017 MRI revealed "some tendinitis and bursitis without any tearing." *Id.* Petitioner was referred to physical therapy for "range of motion and strengthening exercises." *Id.*
- Petitioner underwent an initial physical therapy evaluation for "left shoulder discomfort" on February 23, 2017. Ex. 5 at 67. The therapist detailed Petitioner's current report of "significant and consistent achiness along her anterior arm, however, not past elbow." *Id.* She further noted that Petitioner's range of motion was decreased. *Id.*
- On March 30, 2017, Petitioner again presented to PA Romriell regarding her left shoulder. Ex. 6 at 12. Although she reported a 60-70% improvement in functionality and pain, PA Romriell noted that Petitioner had plateaued in the last week. *Id.*
- Petitioner next presented to PA Romriell on April 27, 2017 for left shoulder pain.
 Ex. 6 at 13. She was diagnosed with left shoulder adhesive capsulitis after a vaccine-induced reaction and was administered an intraarticular injection of Celestone and lidocaine. *Id.*
- The medical note documenting Petitioner's June 1, 2017 appointment with PA Romriell indicates that the intraarticular injection significantly relieved Petitioner's left shoulder pain. Ex. 6 at 14. Improvement of Petitioner's range of motion was also noted. *Id*.
- Petitioner presented to Dr. Russell VanderWilde at Northwestern Orthopaedic Specialists on July 27, 2017. Ex. 6 at 15. Dr. VanderWilde noted that after her December 2016 flu shot, Petitioner "had transient numbness, but then subsequently has had progressive shoulder pain and stiffness that is now getting better." Id. He opined that while "[Petitioner's] sequence of events is certainly unusual . . . I think it anatomically makes sense that the injection were to have been too close to the posterior capsule that it would cause scarring and potential tightness and subsequently the frozen shoulder and impingement problems." Id. Dr. VanderWilde's impression was left shoulder impingement and "left shoulder generalized internal rotation deficit and capsulitis, triggered after a vaccine injection." Id.

- The medical note documenting Petitioner's January 25, 2018 follow-up appointment with Dr. VanderWilde indicates that Petitioner was concerned about nerve injury and abnormal scapular mechanic. Ex. 6 at 6. On exam, Petitioner was found to have "nearly full" range of motion "with slight loss of internal rotation." Id. Dr. VanderWilde also noted that while Petitioner's "[e]xiting nerve" was intact, she had "subtle scapular winging." Id.
- On July 12, 2018, Petition returned to Dr. Russell VanderWilde regarding her left shoulder pain. Ex. 6 at 3-5. Petitioner shared that her pain worsened after participating in physical therapy and noted a "catching sensation" with certain movements. *Id.* at 4. Petitioner was assessed with adhesive capsulitis, a glenoid labrum tear, and shoulder pain. *Id.*
- Petitioner underwent a left shoulder arthrogram on September 4, 2018. Ex. 4 at 716-17. It revealed "significant improvement in the amount of edema within the infraspinatus muscle and tendon as well as imagining improvement in the degree of subacromial/subdeltoid bursitis," when compared to Petitioner's February 2017 MRI. Id. 716.
- On October 4, 2018, Petitioner returned to Dr. VanderWilde regarding her left shoulder pain. Ex 4 at 629-630. His impression was "[l]eft shoulder pain after a vaccine with a history of a frozen shoulder with good motion at this point." *Id.* at 630. Treatment options included the performance of a left shoulder scope and "debridement of the fraying of her labrum." *Id.* Petitioner was advised to follow up as needed. *Id.*

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A Petitioner may prevail on her claim if she has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). If a claimant establishes that she has suffered a "Table Injury," causation is presumed.

Section 11(c)(1) also contains requirements concerning the type of vaccination received and where it was administered, the duration or significance of the injury, and the

lack of any other award or settlement. See Section 11(c)(1)(A), (B), (D), and (E). With regard to duration, a petitioner must establish that she suffered the residual effects or complications of such illness, disability, injury, or condition for more than six months after the administration of the vaccine. Section 11(c)(1)(D).

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table. See Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

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IV. Findings of Fact Regarding Scope of Pain and Limited Range of Motion

Respondent argues that Petitioner has failed to establish that she suffered a Table injury because her symptoms were not limited to her left shoulder. Response at 6. He asserts that Petitioner "constantly described soreness or pain that radiated *down her left arm* and into her hand after receiving her flu vaccine." *Id* (emphasis added).

I find, however, that (for purposes of the Table SIRVA claim), a preponderance of evidence supports the conclusion that Petitioner's injury was limited to her left shoulder, even if pain elsewhere in the arm is documented. Petitioner's medical records consistently document shoulder pain and reduced range of motion, which are specific, contemporaneous evidence consistent with other SIRVA cases. See, e.g., Ex. 4 at 87 (December 22, 2016 medical note documenting Petitioner's complaint of deep pain with shoulder adduction); Ex. 5 at 67 (February 23, 2017 physical therapy note reflecting Petitioner's report of immediate post-vaccination shoulder discomfort and soreness); Ex. 6 at 6 (January 25, 2018 orthopedic note detailing the continuation of Petitioner's left shoulder pain).

Respondent correctly identifies references to soreness and numbness in Petitioner's left hand in the immediate aftermath of vaccination, as well as pain that extended down her arm. Ex. 4 at 72; Ex. 6 at 10, 15. However, while these symptoms were described as transient, Petitioner's left shoulder pain was consistent. See, e.g., Ex. 4 at 87 (December 22, 2016 medical note indicating that while Petitioner's initial report of shoulder pain was accompanied by complaints of arm numbness and tingling, "[t]he numbness and tingling have since resolved "leaving lingering shoulder pain and stiffness."). Moreover, the medical records reflect that Petitioner's treatment was focused on her shoulder symptoms. See, e.g., Ex. 6 at 10 (February 3, 2017 treatment plan detailing MRI testing and evaluation of Petitioner's rotator cuff); Id. at 11 (February 16, 2017 referral to physical therapy for range of motion and strengthening exercises after a finding of left shoulder impingement with tendinitis and bursitis); Id. at 13 (April 27, 2017 orthopedic note detailing the administration of an intraarticular injection to address Petitioner's SIRVA can be disregarded in determining damages in this case.

Accordingly, preponderant evidence establishes that Petitioner's pain was sufficiently "limited" to her left shoulder for a favorable ruling on this SIRVA element.

V. Other Table Requirements and Entitlement

1. Prior Condition

The first QAI requirement for a Table SIRVA is lack of a history revealing problems associated with the affected shoulder which were experienced prior to vaccination and would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i).

Respondent has not contested that Petitioner has met the first requirement under the QAI for a Table SIRVA. Additionally, I do not find any evidence that Petitioner suffered a pre-vaccination history of problems that would explain her post-vaccination shoulder symptoms. Accordingly, I find that Petitioner has met this first criterion to establish a Table SIRVA.

2. Onset

A petitioner alleging a SIRVA claim must also show that she experienced the first symptom or onset within 48 hours of vaccination (42 C.F.R. § 100.3(a)(XIV)(B)), and that her pain began within that same 48-hour period (42 C.F.R. § 100.3(c)(10)(ii) (QAI criteria)).

Respondent does not dispute Petitioner has met this requirement. Additionally, I find that the evidence collectively establishes that her shoulder pain began within 48 hours of receiving the December 9, 2016 flu vaccine. There is no counterevidence undercutting Petitioner's contention that her pain began close-in-time to vaccination, and she consistently attributed his shoulder pain to the flu shot. *See, e.g.*, Ex. 4 at 71 (December 19, 2016 telephone record noting that Petitioner's symptoms "have been going on [since] the date of the shot 12/9."); Ex. 6 at 10 (orthopedic record noting that Petitioner "went in for a flu vaccine and immediately had pain."). Accordingly, I find that Petitioner has met this criterion to establish a Table SIRVA.

3. Other Condition or Abnormality

The last QAI criteria for a Table SIRVA states that there must be no other condition or abnormality which would explain a petitioner's current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent has not contested that Petitioner meets this criterion, and there is no evidence in the record to the contrary. Thus, the record contains preponderant evidence establishing that there is no other condition or abnormality which would explain the symptoms of Petitioner's left shoulder injury.

4. Other Requirements for Entitlement

Even if a petitioner has satisfied the requirements of a Table injury or established causation-in-fact, he or she must also provide preponderant evidence of the additional requirements of Section 11(c), i.e., receipt of a covered vaccine, residual effects of injury lasting six months, etc. See generally § 11(c)(1)(A)(B)(D)(E). But those elements are established or undisputed.

Thus, based upon all of the above, Petitioner has established that she suffered a Table SIRVA, satisfying all other requirements for compensation.³

VI. Conclusion

Based on the entire record, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA. Petitioner is entitled to compensation. A subsequent order will set further proceedings towards resolving damages.

³ Because I have found that Petitioner has demonstrated a Table injury, there is no need to address Petitioner's "causation-in-fact" allegation.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master